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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,404

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Scott Manzo

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01/16/2008

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,404	Applicant(s) MANZO, SCOTT	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 8 and 12-18 is/are rejected.
- 7) ☒ Claim(s) 2-6 and 9-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7, 8, 12, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (5,632,761). With respect to claims 1, 7, 8, and 12, Smith et al. disclose, at least in figures 48-59; an apparatus including a tubular body (1004) having a proximal end, a distal end, and an onion portion (1016) formed near the distal end of the tubular body, the onion portion having a first position within a radial dimension of the tubular body (when fully deflated and undeployed) and a second position outside the radial dimension of the tubular body (when inflated), a sleeve (1002) having an expandable cuff (1024) and having a lumen for receiving the tubular body, and a plunger assembly (1006) for being received in the tubular body, the plunger having a distal end (at 1018) arranged for deploying the onion portion from the first position to the second position; where the onion portion has at least one expanded portion disposed outside the radial dimension of the tubular body when the onion portion is in the second position, where the onion portion has a pair of expanded portions (e.g., proximal and distal portions) disposed outside the radial dimension of the tubular body when the onion portion is in the second position, and where the distal end of the plunger assembly has an engaging element (1022) adapted to selectively couple

with an engaging element (1020 or distal tip of 1004) provided at the distal end of the tubular body. With respect to claim 18, the apparatus includes a tubular body (1030) having a proximal end, a distal end, and an expandable anchor (1018) formed near the distal end of the tubular body, the expandable anchor having a first position within a radial dimension of the tubular body and a second position outside the radial dimension of the tubular body; a sleeve (1002) having an expandable onion (1016) for engaging the second body vessel, the sleeve having a lumen for receiving the tubular body and movable relative to the tubular body with the onion in an expanded condition; and a plunger assembly (1006) for being received in the tubular body, the plunger assembly having a distal end arranged to deploy the expandable anchor. Note: The introductory statement of intended use ("for joining first body vessel and a second body vessel") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Smith et al., which is capable of being used as claimed if one desires to do so.

3. Claims 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Black et al. (6,245,083). Black et al. disclose, at least in figures 4a-4e, a method of joining a first body vessel (32) to a second body vessel (30), where the method includes passing an apparatus through the second body vessel, the apparatus having a tubular body (4) and an onion portion (9), so that the onion portion is received the first body vessel, deploying the onion portion so that the onion portion moves to a position outside the radial dimension of the tubular body, and approximating and joining the first body vessel and the second body vessel, where the approximating includes deploying an

expandable cuff (10) so as to engage the second body vessel; where the onion portion is disposed on the tubular body, where the apparatus includes a sleeve (8) having the expandable cuff and a plunger assembly (6) that is advanced to deploy the onion portion, and where the method includes securing the position of the tubular body and sleeve with respect to one another (see figure 4a or 4b).

Allowable Subject Matter

4. Claims 2-6 and 9-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an apparatus for joining a first body vessel and a second body vessel, where the apparatus includes, inter alia, a tubular body with an onion portion, a sleeve having an expandable cuff and a lumen for receiving the tubular body, and a plunger assembly received in the tubular body, where the onion portion comprises a plurality of ribs defining a plurality of longitudinally oriented slots, where the onion portion has a plurality of barbs for engaging the first body vessel, the barbs being arranged to face in a proximal direction when the onion portion is in the second position; or where the onion portion comprises a plurality of ribs.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

6. Applicant's arguments filed on October 12, 2007 have been fully considered but they are not persuasive. The Applicant has asserted that the references of Smith and Black do not include structures associated with an "onion portion." The Examiner respectfully disagrees. Although the specification has described the "onion portion" as including *an* embodiment having a "plurality of radially formed, longitudinally oriented, elongated slots," the specification also describes the "onion portion" as having a first position "within the radial dimension of the tubular body" and a second position outside of the "radial dimension of the tubular body." Thus, the "onion portion" is apparently an expandable portion on the tubular body, which in the second position, forms a bulbous element as seen in the figures—an element analogous to an onion, which the ENCARTA World English Dictionary (2007) defines as an "edible bulb used as a vegetable." Clearly, the Applicant is not applying a vegetable as a medical device; and since the Applicant has not explicitly and precisely defined the "onion portion" or the "onion sleeve portion," the Examiner has deemed the balloons of Smith and Black to be "onion portion[s]." That is, the balloons are each attached to a tubular body, and each balloon has first and second positions as mentioned above. Each balloon also has a bulbous (i.e., onion) shape in the second position. Thus, the balloons comprise "onion portion[s]," when the claims are given their broadest reasonable interpretation.

Moreover, the Applicant has pointed out that the "onion portion" is formed of steel or titanium, which is not ordinarily used in a balloon. On the contrary, neither the claims nor the specification require exclusively steel or titanium as the "onion portion" material.

The specification states that the material is a "medical grade material," where steel and titanium are only given as examples of such material. The balloons of Smith and Black are formed of "medical grade material." The Applicant is reminded that it is the language itself of the claims which must particularly point out and distinctly claim the subject matter which the applicant regards as his invention, without limitations imported from the specification, whether such language is couched in terms of mean plus function or consists of detailed recitation of the inventive matter. Limitations in the specification not included in the claim may not be relied upon to impart patentability to an otherwise unpatentable claim.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

January 14, 2008